

REMARKS

The Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the reasons that follow.

I. Status of the Claims

Original claims 1 and 11 are each combined with claims 3-5 and are represented as new independent claims 14 and 20, respectively. The recitations regarding the different hydroxypropyl celluloses and polyvinyl alcohol-polyethylene glycol graft copolymer can be found in, for example, paragraph [0032] in the Specification as published, and original claim 3. The dependent claims of original claim 1 are amended accordingly to reflect the amendments to claim 1. All previous claims are thus cancelled. The Applicants reserve the right to pursue the subject matter of the cancelled claims in a subsequent continuation and/or divisional application. No new matter is introduced, and claims 14-20 are currently pending to be examined on their merits.

II. Claim Rejection – 35 U.S.C. § 112

Claims 1 and 3-4 are rejected under 35 U.S.C. § 112, ¶1, as allegedly being indefinite. Particularly, the Office alleges that the recitations of “[a] production method of a coated preparation,” “coating with an aqueous dispersion of...,” and “low viscosity” are not clear. Additionally, the Office requests that SL and SSL be spelled out.

While not acquiescing to the grounds of the rejection, all of the pending claims have been amended. At least in view of the foregoing, the Applicants respectfully submit that the rejection is now moot.

III. Claim Rejection – 35 U.S.C. § 102

Claims 1, 5-8, and 11 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Cutie (WO 01/82875). Claims 1, 5-8, and 11 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Kositprapa (US 2004/0106660). Claims 1, 5, and 9-11 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Sugiyama (US 2003/0060488).

While not acquiescing to the grounds of the rejection, all of the pending claims have been amended. Particularly, claims 3-4, which are not rejected under 35 U.S.C. §§ 102(b), 102(e), are combined with original independent claims 1 and 11 and represented as independent claims 14 and 20. At least as a result of the amendments, none of the cited references teaches each and every element as recited in claims 14 and 20. Thus, the teachings of none of these references can anticipate independent claims 14 and/or 20, or any of their dependent claims.

Therefore, at least in view of the foregoing, the Applicants respectfully request that the rejection be withdrawn.

IV. Claim Rejection – 35 U.S.C. § 103

Claims 1 and 5-11 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sugiyama in view of Cutie or Kositprapa. Claims 1, 3-8, and 11 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Cutie or Kositprapa in view of Fujinaga (2004/0092480). The Applicants respectfully traverse.

With respect to the rejection of claims 1 and 5-11, the Applicants note that the Office cited Cutie as “Timmings et al. US 2003/0060488 (‘488).” Page 7, Office Action. The Applicants assume that the Office refers US 2003/0060488 to Sugiyama, as above, and thus provide remarks accordingly. The Applicants herewith also provide the standard for determination of obviousness as delineated by the U.S. Supreme Court.

(i) Current Obviousness Standard

The Supreme Court recently reaffirmed the Graham factors for determining obviousness in *KSR Int'l Co. v. Teleflex Inc.* (No. 04-1350) (U.S., April 30, 2007). The Graham factors, as outlined by the Supreme Court in *Graham et al. v. John Deere Co. of Kansas City et al.*, 383 U.S. 1 (1966), are: 1) determining the scope and contents of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; 3) resolving the level of ordinary skill in the pertinent art; and 4) evaluating evidence of secondary consideration. The Supreme Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a), and held that the proper inquiry for determining obviousness is whether the improvement is more than the predictable use of prior art elements according to their established functions. The Court noted that it is "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed, and specifically stated:

Often, it will be necessary . . . to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was ***an apparent reason to combine the known elements in the fashion claimed*** by the patent at issue. To facilitate review, this analysis should be made explicit.

KSR Int'l Co. v. Teleflex Inc., slip op. at 14 (emphasis added). As discussed below, the cited art cannot render the claimed invention obvious.

(ii) Present Claims Are Non-Obvious over Sugiyama in View of Cutie or Kositprapa

While not acquiescing to the grounds of rejection, claims 3-4, which are not rejected under 35 U.S.C. § 103(a) have been combined with original claims 1 and 11 as new independent claims 14 and 20. At least in view of the amendments, none of Sugiyama, Cutie, and Kositprapa teaches or suggests every element as recited in independent claims 14 and 20. In particular,

nowhere does any of these cited references teach or suggest a coating material selected from the groups as recited in claims 14 and 20. Because none of these references teach or suggest such recitations, one of ordinary skill in the art would not have a reason to combine the teachings thereof. *See KSR Int'l Co.* Thus, Sugiyama, Cutie, and Kositprapa, alone or in combination, cannot render independent claims 14 and 20 and any of their dependent claims obvious.

(iii) Present Claims Are Non-Obvious over Cutie or Kositprapa in View of Fujinaga

The present claims are also non-obvious over Cutie, Kositprapa, and Fujinaga. In fact, one of ordinary skill in the art would not have a reason to combine the teaching of Fujinaga with that of Cutie or Kositprapa.

As already provided previously, Cutie and Kositprapa, alone or in combination, cannot render the present claims obvious because neither of them teaches or suggests the methods as claimed. Fujinaga discloses using specific hydroxypropyl celluloses (HPC) to solve the problem specific to a biphenylamidine derivative. See paragraphs [0003]-[0005] and [0010]-[0011], Fujinaga. Fujinaga also discloses using HPC-L and HPC-SL and teaches in its Example 7 that a preparation using HPC-L is desirable in the dissolution property of the biphenylamidine derivative.

However, nowhere does Fujinaga disclose the methods as recited in independent claims 14 or 20. Particularly, Fujinaga does not at all teach or suggest a method using a coating material selected from the groups as presently claimed, let alone disclose the unexpected desirable results as provided by the presently claimed methods, particularly with respect to a preparation using HPC-SL as being superior to one using HPC-L in the dissolution property of pioglitazone hydrochloride. As demonstrated in Experimental Examples 2 and 3 in the present Specification, a preparation using HPC-SL is superior to one using HPC-L in the dissolution property of pioglitazone hydrochloride. Such unexpected superiority of HPC-SL to HPC-L is not disclosed or even suggested by Fujinaga.

Thus, the Applicants respectfully submit that the Office's assertion “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute one HPC into the pharmaceutical formulations of '875 [Cutie] or '660 [Kositprapa] with the specific HPC disclosed by '480” [Fujinaga] (page 11, Office Action) is only speculative. In fact, the Applicants respectfully submit that one of ordinary skill in the art would not have had a reason to apply the HPC of Fujinaga, which is preferable to the biphenylamidine derivative, to the pioglitazone hydrochloride of Cutie or Kositprapa. *See KSR Int'l Co.* Additionally, even assuming, *arguendo*, the teachings of these references were combined, one of ordinary skill in the art would not have expected to reach the same desirable results as presently claimed. Thus, Fujinaga, Cutie, and Kositprapa, alone or in combination, cannot render the present claims obvious.

Therefore, at least in view of the foregoing, the Applicants respectfully request that the rejection be withdrawn.

CONCLUSIONS

The Applicants believe that the present application is now in condition for allowance and thus respectfully request favorable reconsideration of the application.

The Office is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By 

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